DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Meg Carr
Senior Director, Regulatory Affairs
TriVascular, Inc.
3910 Brickway Blvd.
Santa Rosa, CA 95403

OCT – 5 2012

Re: P120006
Ovation Abdominal Stent Graft System
Filed: April 11, 2012
Amended: June 8, 2012, July 12, 2012, and July 27, 2012
Procode: MIH

Dear Ms. Carr:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Ovation Abdominal Stent Graft System. This device is indicated for treatment of patients with abdominal aortic aneurysms having vascular morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with vascular access techniques, devices, and/or accessories,
- Non-aneurysmal proximal aortic neck:
  - with a length of at least 7 mm proximal to the aneurysm,
  - with an inner wall diameter of no less than 16 mm and no greater than 30 mm, and
  - with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm,
- Adequate distal iliac landing zone:
  - with a length of at least 10 mm, and
  - with an inner wall diameter of no less than 8 mm and no greater than 20 mm.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA

requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 3 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" (please use this title even if the specified interval is more frequent than one year) and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You have agreed to provide the following data as part of the Annual Report:

1. You will provide a clinical update to physician users at least annually. At a minimum, this update will include, for your long-term post-approval study cohort, a summary of the number of patients for whom data are available, with the rates of aneurysm-related mortality, aneurysm rupture, secondary endovascular procedures, conversion to surgical repair, complications, endoleak, aneurysm enlargement, prosthesis migration, and patency. Reports of losses of device integrity, reasons for conversion and causes of aneurysm-related death and rupture are to be described. A summary of any explant analysis findings is to be included. Additional relevant information from commercial experience within and outside of the U.S. is also to be included. The clinical updates for physician users and the information supporting the updates must be provided in the Annual Report.

In addition to the Annual Report requirements outlined above, you agree to conduct a post-approval study (PAS) to evaluate the long-term safety and effectiveness of the Ovation Abdominal Stent Graft System for the treatment of infra-renal abdominal aortic aneurysms.

1. *Long-Term Follow-up Study:* This will be a prospective, consecutively enrolling, single-arm, multicenter study that will consist of continued follow-up of all available subjects from the pivotal study and the continued access study, as well as newly enrolled (*de novo*) subjects from this PAS and the HDE PAS (H100008). A total of 320 subjects will be enrolled with at least 192 evaluable at five years post-implantation. A minimum of 59 *de novo* subjects will be enrolled from a minimum of 15 investigational sites across the U.S.

The primary safety endpoint of the study is freedom from aneurysm-related mortality at five years post implantation, which will be compared to a performance criterion of 92%. Aneurysm-related mortality is defined as:

> *Death from rupture of the abdominal aortic aneurysm or from any procedure intended to treat the AAA. If a death occurred within 30 days of any procedure intended to treat the AAA or within the hospital stay if the patient was not discharged within 30 days, then it is presumed to be aneurysm-related.*

Secondary endpoints through five years will include mortality rates (AAA-related and all-cause), serious adverse events (SAE), device patency, conversion to surgical repair, endoleak, AAA enlargement, stent graft migration, device integrity, secondary endovascular procedures and aneurysm rupture.

2. *Evaluation of training program:* This analysis will evaluate your training program by comparing the incidence of the following as a function of physician experience:

   - at implant: technical failure, type I endoleak, and the use of accessory devices implanted in the treatment area; and

   - through 30 days: secondary endovascular procedures, device-related serious adverse events, and the following events: thromboembolic, paralysis, paraparesis, renal, stroke, claudication, and ischemic colitis.

   The physicians involved in this comparison include all those who treated the subjects included in the PAS, the previously enrolled subjects, and *de novo* subjects. The physicians' experience will be categorized into two groups:

   a. those who have completed fewer than 20 endovascular repairs of AAA with any endovascular graft in the 2 years preceding participation in the Ovation physician training program, and

   b. those who completed equal to or more than 20 said cases.

   Additionally, if any insights are obtained regarding your training program, you will provide a discussion of that in the post-approval study report. Should modifications be necessary to the training program, you will describe and provide the appropriate rationale for each modification within the Annual Report to your PMA.

Please be advised that the results from this study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement.

FDA would like to remind you that you are required to submit PAS Progress Reports every six months during the first two years of the study and annually thereafter. The reports should clearly

be identified as Post-Approval Study Report. Two copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you;

however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive (general information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm; clinical and statistical data: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm)

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If you have any questions concerning this approval order, please contact Tina M. Morrison, Ph.D. at tina.morrison@fda.hhs.gov or (301) 796-6310.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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